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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/544,910	04/07/2000	Yadong Huang	06510/121US1	2429

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BOZICEVIC, FIELD & FRANCIS LLP
1900 UNIVERSITY AVENUE
SUITE 200
EAST PALO ALTO, CA 94303

EXAMINER	
SHIN, DANA H	

ART UNIT	PAPER NUMBER
1635	

DATE MAILED: 03/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/544,910	HUANG ET AL.	
	Examiner	Art Unit	
	Dana Shin	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 December 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4-8 and 11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1, 4-8 and 11* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1, 4-8, and 11 are drawn to a method for reducing the plasma level of VLDL in a host, said method comprising administering the said host an effective amount of an antisense nucleic acid, wherein said antisense nucleic acid reduces the amount of plasma active apoE resulting in the reduction of the plasma level of VLDL by at least two fold , classified in class 435, subclass 325.

II. Claims 1, 4-8, and 11 are drawn to a method for reducing the plasma level of VLDL in a host, said method comprising administering the said host an effective amount of a ribozyme, wherein said ribozyme reduces the amount of plasma active apoE resulting in the reduction of the plasma level of VLDL by at least two fold , classified in class 435, subclass 325.

III. Claims 1, 4-8, and 11 are drawn to a method for reducing the plasma level of VLDL in a host, said method comprising administering the said host an effective amount of an antisense conjugate wherein said antisense conjugate reduces the amount of plasma active apoE resulting in the reduction of the plasma level of VLDL by at least two fold , classified in class 435, subclass 325.

The inventions are distinct, each from the other because:

The invention of group I is related to that of group II as related processes. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the methods of groups I and II are related since they are directed to reducing the plasma level of VLDL in a host. However, these methods are distinct because the method of group I utilizes an antisense nucleic acid as the agent that reduces the plasma level of VLDL in a host while the method of group II utilizes a ribozyme as the agent. The antisense nucleic acid of group I mediates inhibition of gene translation by a sequence-specific binding of an antisense oligonucleotide to target mRNA, activating the RNase H cleavage activity. The ribozyme of group II is a catalytically active oligonucleotide that possesses inherent RNA cleaving activity. By virtue of different structures and modes of actions of the agents of groups I and II, the inventions of groups I and II do not overlap in scope; they are not obvious variants; and they have a materially different design and mode of operation. Furthermore, because these inventions are divergent and non-coextensive for the reasons given above and the inventions require different keyword searches and art against one would not necessarily apply against another (see MPEP § 808.02), to search them together represent a search burden on the examiner and are properly restricted therefore.

The invention of group I is related to that of group III as related processes. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are

either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the methods of groups I and III are related since they are directed to reducing the plasma level of VLDL in a host. However, these methods are distinct because the method of group I utilizes an antisense nucleic acid as the agent that reduces the plasma level of VLDL in a host while the method of group III utilizes an antisense conjugate. The antisense conjugate of group III comprises conjugating small molecules and large biomacromolecules to antisense oligonucleotides to improve therapeutic potential of the antisense oligonucleotides of group II through enhancing the RNase H mode of action via conjugate formation. Since the structure and function of the antisense oligonucleotide of group I are different from those of the antisense conjugate of group III, these inventions do not overlap in scope; the inventions are not obvious variants; and these inventions have a materially differente design, mode of operation, function, and effect. Furthermore, because these inventions are divergent and non-coextensive for the reasons given above and the inventions require different keyword searches and art against one would not necessarily apply against another (see MPEP § 808.02), to search them together represent a search burden on the examiner and are properly restricted therefore.

The invention of group II is related to that of group III as related processes. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the methods of groups II and III

are related since they are directed to reducing the plasma level of VLDL in a host. However, these methods are distinct because the method of group II utilizes a ribozyme as the agent that reduces the plasma level of VLDL in a host while the method of group III utilizes an antisense conjugate. The ribozyme is a catalytic nucleotide with inherent RNA cleavage activity, while the antisense conjugate of group III mediates its inhibitory effects through recruiting and promoting the RNase H mode of action. Moreover, the methodology of using a ribozyme cannot be substituted by that of using an antisense conjugate. Since the structure, mode of action, and methodology of the ribozyme of group II are different from those of the antisense conjugate of group III, these inventions do not overlap in scope; the inventions are not obvious variants; and these inventions have a materially different design, mode of operation, function, and effect. Furthermore, because these inventions are divergent and non-coextensive for the reasons given above and the inventions require different keyword searches and art against one would not necessarily apply against another (see MPEP § 808.02), to search them together represent a search burden on the examiner and are properly restricted therefore.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dana Shin whose telephone number is 571-272-8008. The examiner can normally be reached on Monday through Friday, from 8am-4:30pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Dana Shin
Examiner
Art Unit 1635

JAMES SCHULTZ, PH.D.
PRIMARY EXAMINER